**Questions for EPA EFED from CLA ESPSG for Discussion October 24th**

- There seems to be general agreement among stakeholders that the process utilized for the endangered species assessments (ESAs) conducted for the 3 OPs will need revisions to make the assessment process sustainable. Would you please comment on ideas that EFED has been discussing to address process improvements in future ESAs?
- Similarly, what are the pieces of an ESA that tend to be most time/resource intensive and what is EFED's thoughts on how these pieces can be improved to allow the ESA process to be more efficient?
- EPA has recently recognized registrants as 'applicants' in the ESA consultation process. Are there any specifics on what form this interaction would take (e.g., specifically how and at what timepoint(s) in the process can applicants interact with EPA and/or the Services, and what information / data would the applicant be providing)?
- Does EFED have any proposals for the types of public stakeholder engagement forums that would be the most efficient & effective for EFED personnel as the process improvements in the ESAs are being developed, considered, and/or implemented?
- Has EFED been involved or benefited from the work of the Interagency Work Group (IWG)?
- At the August ACS meeting in Boston, Rochelle Bohaty presented a framework for using surface water data within a tiered water exposure assessment process. This was a very interesting presentation, leading to the following questions:
    - Has EFED developed a timeline for proving stakeholders with the specific guidance that EPA would use in implementing SeaWave-QEX, the subject of Rochelle's presentation?
    - Does EFED still plan on taking SeaWave-QEX and its use in the risk assessment process to a Scientific Advisory Panel in 2019?
    - Does EFED have any plans for using SeaWave-QEX or other updated exposure models within ESA (since discussions thus far appear focused on drinking water for SeaWave-QEX)?
    - As there is no completed tiered process for water exposure for use within ESA, does EFED have plans on how any types of water exposure refinements might be utilized within ESA?
    - Rochelle has presented SeaWave-QEX as a component within a larger water exposure process that would also use the input parameter-based modeling of SAM. Does EPA have specific plans for completing the development of SAM?
    - What types of efforts from stakeholders regarding the tiered modeling approach would be helpful to EFED at this point in time?
- In July 2017, The Environmental Protection Agency Issued the Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act as a new final rule (40CFR 702.43). This rule included a number of requirements that, if adopted by Office of Pesticide Programs, would likely improve upon current practice in providing more defensible and informative risk assessments as a basis for risk management decisions, including;
        - Adoption and application of a weight of evidence framework as defined by EPA
        - Rigorous documentation of data quality criteria applied to, and transparent presentation of, supporting/refuting evidence within the weight of evidence framework
        - The inclusion of quantitative uncertainty analysis as appropriate/feasible
        - Thorough documentation of sources of uncertainty and variability

        - Characterization of, and implications from, default assumptions, scenarios and data used by risk assessors
    - Has OPP reviewed the aforementioned rule and considered the adoption of the TSCA requirements as part of standard practice in environmental risk assessments produced by the Office of Pesticide Programs? If not, does OPP plan to? Has the Agency considered similar measures that could be readily adopted that might make Agency decisions less susceptible to lawsuits, misinterpretation or mischaracterization of EPA risk analysis by a third party?

- It is our understanding OPP is re-reviewing the EDSP List 1 Weight of Evidence (WoE) evaluations. Can you update us on what led to the re-evaluation, and how the re-evaluation is being performed including who from EFED is involved?
    - Is there anything EFED has learned from the EDSP WoE process that can be applied to ESAs / biological evaluations?

- With respect to data evaluation records (DERs) CLA would greatly appreciate if EPA could clarify the following:
    - **Access:** Is there a possibility to develop a more efficient and transparent mechanism whereby Registrants could gain more timely, access to DERs generated for Registrant-submitted data or other data relevant to the corresponding risk assessment?
    - **Templates:** Does EPA use the same standard templates as those provided or used by EPA contractors for evaluation of data? Are the same templates used for all sources of data to be considered within a risk assessment (e.g. Registrant submitted data, peer-reviewed data etc.)? If not, is there an opportunity to implement consistency within the DER process?
    - **Review:** Are there legal or regulatory impediments to providing registrants with an opportunity to respond to a DER to correct errors or designation (e.g. quantitative or qualitative) prior to implementation within a risk assessment or during the response period for review of risk assessment materials (e.g. risk assessments, problem formulations etc.)
    - **Transparency:** Is it possible to provide the specific criteria used in the study evaluation, the study review and classification process and how DERs are interpreted, as well as how DERs are incorporated into risk assessments? What is the process for documenting changes in classification or conclusions that override the DER recommendation(s)?